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10/630,536	07/29/2003	Paula M. McCready	IL-11030	3210

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EXAMINER

BAUSCH, SARA E L

ART UNIT	PAPER NUMBER
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1634

MAIL DATE	DELIVERY MODE
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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/630,536

Applicant(s)

MCCREADY ET AL.

Examiner

Sarae Bausch

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 October 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4-15 is/are pending in the application.
- 4a) Of the above claim(s) 4-7, 9, 10, 14 and 15 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 8 and 11-13 is/are rejected.
- 7) ☒ Claim(s) 11-13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- ☐ Notice of Informal Patent Application
- ☐ Other: _____

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DETAILED ACTION

1. Currently, claims 4-15 are pending in the instant application. Claim 1-3 and 16-17 have been canceled. Claims 4-7 are withdrawn. Claims 9-10 and 14-15 are withdrawn as being drawn to a non-elected invention, see page 3 of the office action mailed 08/07/2006. This action is written in response to applicant's correspondence submitted 10/03/2007. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. The following rejections are either newly presented or are reiterated from the previous office action. Any rejections not reiterated in this action have been withdrawn as necessitated by applicant's amendments to the claims. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

This action is Non-Final.

2. Currently, claims 8, 11-13 and the set of SEQ ID No. 4 and 8 and the set of oligonucleotides SEQ ID No. 1-3 and 5-7 are under examination on the merits.

Withdrawn Rejections

3. The rejections of claims 8 and 11-13, under 35 U.S.C. 112(2) made in section 7 and 8 of the previous office action mailed 05/03/2007, is withdrawn in view of the amendment to the claims.

4. The rejections of claims 8 and 11-13, under 35 U.S.C. 112(1), made in section 9 of the previous office action mailed 05/03/2007, is withdrawn in view of the amendment to the claims and support for the amendment is found on pg. 4 and para. 15-16.

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5. The rejections of claims 8 and 11-13, under 35 U.S.C. 103(a), made in section 11 of the previous office action mailed 05/03/2007, is withdrawn in view of the arguments made on page 8 of the remarks mailed 10/03/2007. Specifically the traversal that the species is not rendered obvious by the genus, the genome of *Y. pestis* is found persuasive (see pg. 8).

6. The objection to the specification in section 5 of the previous office action mailed 05/03/2007 is withdrawn in view of the amendment to the abstract.

Claim Objections

7. Claims 11-13 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Specifically, claim 11 recites a set of oligonucleotides comprising a polynucleotide fragment of each of the isolated polynucleotides of the set of polynucleotides of claim 8. Claim 8 requires a set of polynucleotides comprising isolated polynucleotides consisting of SEQ ID no. 4 and SEQ ID no. 8. Claim 11 does not further limit claim 8 as claim 11 is broadening and allows for multiple polynucleotides, with multiple fragments of SEQ ID no. 4 and SEQ ID no. 8. Claim 11 yields more polynucleotides than claim 8 requires and therefore is not further limiting.

New Grounds of Rejection

Claim Rejections - 35 USC § 112- New Matter

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 8 and 11-13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection includes a new matter rejection.

Claim 8 is drawn to a composition comprising a first and second isolated polynucleotide of SEQ ID No. 4 *or* a complement thereof and SEQ ID No. 8 *or* a complement thereof. The recitation of “a complement” broadly encompasses any two or more nucleotides of SEQ ID No. 4 and SEQ ID No. 8. Additionally the recitation of “a complement” broadly encompasses fragments of SEQ ID no. 4 and 8 which includes variants mutants, and homologs of SEQ ID No. 4 and SEQ ID No. 8 with a minimum of two nucleotides of SEQ ID No. 4 and SEQ ID No. 8 that are not described in the specification.

While the specification teaches SEQ ID NO 1-4 and 6-8, the specification provides insufficient written description to support the broad genus encompassed by the claims. The instant claims are drawn to undisclosed sequences encoding modification that have not been contemplated. The specification provides insufficient written description to support the genus

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encompassed by the claim. Absent a written description, the specification fails to show that the applicant was "in possession of the claimed invention" at the time the application for the patent was filed. Further, the genus of polynucleotides comprised by the claim is a large variable genus and also reads on undisclosed genomic sequences. The specification only discloses a selected number of species of the genus; i.e. SEQ ID NO 1-4 and 6-8, which is insufficient to put one of ordinary skill in the art in possession of all attributes and features of all species within the genus, which include full length genes, mutants, variants, and homologs. Thus one skilled in the art cannot reasonably conclude that applicant had possession of the claimed genomic sequences, as well as mutants, variants, and homologs from any source at the time the instant application was filed with respect to claims 8 and 11-13.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

With the exception of SEQ ID NO: 1-4 and 6-8; the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The nucleic acid itself is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993), and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30

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USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, *University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993). Accordingly, "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1170, 25 USPQ2d at 1606.

Accordingly, the specification does not provide written description of the invention of claims 8 and 11-13. It is noted this rejection can be overcome by reciting "SEQ ID no. 4 or the complement thereof... SEQ ID No. 8 or the complement thereof".

The newly amended claim(s) contain subject matter that changes the scope of the claim and is not supported in the specification and raises issues of new matter. This rejection is newly presented.

Claim 11 recites "fragments that are 19 to 33 nucleotides in length" (amended on 02/12/07). This recitation is not supported in the specification and raises the issue of new matter. The specification does not provide support for a range of nucleotide lengths. The specification does provide support for the specific length of 19, by SEQ ID No. 10 and the length

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of 33 nucleotides by SEQ ID no. 3, which provides support for a set of oligonucleotides that are 19 or 33 nucleotides in length but does not provide support for the range of nucleotide lengths from 19 to 33 nucleotides. Therefore the support of SEQ ID No 10 and SEQ ID no. 3 provides support the specific lengths but is not sufficient to provide a range of nucleotides as claimed.

Neither the SEQ ID no. disclosed nor the specification provide support or contemplate a range of nucleotide lengths.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Hu et al. (J. Bacteriol. 1998, vol. 180, pages 5192-5202).

Hu et al. teach analysis of the pMT1 virulence associated plasmid of *Yersinia pestis*. The plasmid, pMT1 comprises nucleotides 85237-85136 which are identical to SEQ ID No. 4 and nucleotides 13354-13500, which are identical to SEQ ID No. 8 (alignment provided on 08/07/2006). Hu et al. teach the plasmid, pMT1, which is double stranded and inherently is “a complement” of SEQ ID no. 4 and SEQ ID no. 8. The recitation of “a set of oligonucleotides comprising SEQ ID No. 4 *or* a complement thereof..... SEQ ID No. 8 *or* a complement thereof” is broadly interpreted to encompass a set of oligonucleotides that comprises any two or more nucleotides of SEQ ID No. 4 and SEQ ID No. 8 which is anticipated by Hu et al.

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This rejection can be overcome by reciting "SEQ ID no. 4 or the complement thereof... SEQ ID No. 8 or the complement thereof".

12. Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Brennan (US Patent 5474796).

With regards to claim 8, Brennan teaches an array having every possible permutation of a 3mer and a 10mer oligonucleotide (see example 4, column 9, lines 15-60, figure 1). Claim 8 is drawn to "a set of oligonucleotides comprising.... SEQ ID No. 4 or a complement thereof.... SEQ ID No. 8 or a complement thereof" which is broadly interpreted to encompass a set of oligonucleotides that comprises any fragment of two or more nucleotides and can broadly encompasses any magnitude and/or content that comprise at least two nucleotides of SEQ ID No 4 and 8, which is anticipated by Brennan.

This rejection can be overcome by reciting "SEQ ID no. 4 or the complement thereof... SEQ ID No. 8 or the complement thereof".

Conclusion

13. No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarac Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at (866) 217-9197 (toll-free).

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Sarae Bausch/
Sarae Bausch, PhD
Examiner
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